



FY 2003
PROGRAM ELEMENT EVALUATION REPORT
OF THE
GROWING AREA CLASSIFICATION ELEMENT
SHELLFISH SANITATION PROGRAM
DEPARTMENT OF MARINE RESOURCES
STATE OF MAINE

PREPARED BY

PETER N. KOUFOPOULOS
REGIONAL SHELLFISH SPECIALIST
NORTHEAST REGION FIELD OFFICE
FOOD AND DRUG ADMINISTRATION

ON

October 22, 2003

PROGRAM ELEMENT EVALUATION REPORT

STATE: Maine

DATES OF EVALUATION: June 9, 2003 - June 26, 2003

PROGRAM ELEMENT EVALUATED: Growing Area Classification

A. Status of Deficiencies from Last Program Evaluation

The FY 2002 evaluation of the Maine Department of Marine Resources (DMR) Growing Area Program found that DMR was in compliance with the National Shellfish Sanitation Program (NSSP) Model Ordinance (MO). The Growing Area Program was in compliance; although four recommendations were cited to help the state strengthen its program.

Below are the four recommendations noted in the FY 2002 evaluation followed by the states response to each recommendation:

1. *FDA recommends that the DMR reassess the closure zone around the York Harbor Marina in the York River. Without further written documentation and based on current information, the existing closure zone should be increased to include the waters along Stage Neck in its entirety.*

The marina closure for the York Harbor Marina was increased to include the Stage Neck area of the York River on October 3, 2002.

2. *FDA recommends that the DMR reassess the closure zone around both the South Freeport and Strouts Point Marinas, located in the Harraseeket River. During the field visit, it was noted that shellfish harvesting occurs in a cove directly north and adjacent to the marina proper. Without further written documentation and based on current information, the existing closure zone should be increased to include the conditionally approved waters north of the marinas.*

The ME Department of Environmental Protection engineers were contacted in September 2002 to request their assistance with determining a 400:1 closure zone near the sewage treatment outfall which is also located near the two marinas. Currently the closure within the river has been increased and shellfish can only be harvested during the daytime hours when the plant has staff on-site

3. *FDA recommends that the DMR reassess the closure zone around Paul's Marina in Merepoint Bay. Without further written documentation and based on current information, the existing closure zone should be increased, at the southern portion of the mooring field, to include as much of the calculated closure as possible.*

The marina closure for Paul's Marina in Merepoint Bay, Brunswick was increased to include the southern portion of the mooring field on October 17, 2002.

4. *FDA recommends that the DMR create a statewide standard for all computer generated maps (i.e. GIS based in such programs as ArcView™). The above classification maps were provided to this office by the two regional DMR field offices. As observed, there is no consistency in their appearance. A harvester accustomed to the vertical lines representing a conditionally approved area in one town might unknowingly find themselves harvesting shellfish for human consumption in a restricted area in another town. All shellfish programs rely heavily on the sharing of information between intrastate agencies. The lack of consistent data representation will slow, and even prevent, the needed interstate exchange of information between the DMR and other state shellfish programs. A single map standard would be charged with such activities as implementing a consistent map resource book to be used by sample collection teams, marine patrol units, volunteer workers and to be accessed by the general public through the internet.*

The DMR is exploring this recommendation. Computer generated maps are being used in most aspects of the shellfish program. Preliminary meetings have been scheduled to determine the feasibility of updating and cross-referencing shellfish growing areas, patrol areas, water quality sampling stations, pollution sources and harvester information.

B. Total Number and Identification of Growing Areas Evaluated

The Maine Department of Marine Resources monitors 45 separate Shellfish Management Areas. Twelve of the Shellfish areas were selected to be evaluated. The number of evaluations is based upon a representative sampling plan designed to provide a 95 percent probability of detecting a 20 percent or greater defect level. The selection of the 12 growing areas was performed by Peter Koufopoulos, the Northeast Regional Shellfish Specialist. Mr. Koufopoulos utilized the Excel database program and performed a random number query. The selected growing areas are listed below.

Shellfish Management Areas

West - Boothbay Harbor Office

WG	Saco Bay
WI	Casco Bay
WM	Kennebec River
WS	Medomak River
WT	Friendship
WZ	North Haven/Vinalhaven

East - Lamoine State Park Office

WX	Penobscot River
EC	Deer Isle/Stonington
EG	Union River
EL	Narraguagus River
EP	Englishman's Bay
ES	Cutler Coast

C. State Program Areas in Compliance and Program Areas Evaluated

The Maine DMR follows the NSSP Model Ordinance (MO) regarding the completion timeframes for all required reports. Currently the staff are required to complete the Sanitary Surveys every 12 years, the Triennial Reports every 3 years and the Annual Updates every year. Internal DMR policy states that all reports are to be formatted to meet the requirements of the MO. Conditional area management plans are re-evaluated on an annual basis. Information gathered from the management plan review is included in the Annual Update. All Annual Updates are completed by February 28th each year for the previous calendar year.

All conditionally managed areas that were reviewed during this evaluation period were closed according to the defined conditional management plan in the sanitary survey. DMR also closes Approved waters during emergency conditions, typically heavy rainfall events. Areas closed due to management plan violations are normally closed for a minimum of fourteen days after the event. The area will reopen only after acceptable water samples and/or shellfish meat results are received and evaluated. The affected area will reopen when the fourteen-day period has elapsed or when meat samples have demonstrated that contaminants have been reduced. There are currently several studies underway in hopes of documenting a relationship between fecal coliform bacteria levels in the water and fecal coliform bacteria levels in the adjacent shellfish. Any correlation made could reduce the effort of future sampling and also allow the fourteen-day cleansing period to be shortened.

The Maine DMR is in the process of finalizing their re-write of the state's shellfish regulations. As part of this process, various members of the Public Health Division are attending and conducting Public Information Meetings. These meetings are being held at multiple locations around the state. Industry members have been notified and even encouraged to attend these moderated meetings in order to learn how the new regulations may affect them. These meetings allow the industry an opportunity to provide feedback on the proposed regulations at the beginning of the process. Any comments and suggestions offered by the industry members will be considered and changes can be made before the formal Public Hearings begin. The DMR have provided the industry members with an opportunity to voice their concerns, this openness has allowed the industry to develop a sense of ownership of the new regulations to which they will be held.

1. Sanitary Survey - General

Written Sanitary Survey reports were present and completed for all 12 management areas that were reviewed. DMR generally follows the format described in the NSSP MO Guidance Document A.3. During discussions with staff members it was noted that some overdue surveys (in excess of 12 years) were in the process of being finalized. The reviewed survey reports did have all of the required sections and subsections. It was noted, however, that the Hydrographic and Meteorological section, and the concluding subsections throughout the report, were sparse and devoid of strong information upon which to make decisions regarding proper classification.

2. Sanitary Survey - Required

Sanitary Surveys are completed on all Shellfish Management Areas prior to the harvest of shellstock for human consumption. A Sanitary Survey along with its associated shoreline survey is used to properly classify an area as Approved, Conditionally Approved, Restricted or Conditionally Restricted.

3. Sanitary Survey - Performance

The DMR schedule Sanitary Surveys to be completed once every 12 years for each Shellfish Management Area. The DMR stagger the triennial reviews so they may be completed in a timely fashion, once every three years. The water quality staff recognizes that if a Sanitary Survey or a Triennial Review are not completed within the specified time frames then the Shellfish Management Area shall be placed in the closed status pending completion of the reports.

Per DMR internal guidelines, the Annual Updates are complete by February 28 for the previous calendar year. It was noted during the evaluation that some of the Annual Updates had not been completed. Annual Updates require staff to review important performance standards, sampling data and pollution source information to determine if a downward trend in water quality is occurring. It is vital that these assessments are completed in a timely fashion each year.

Domestic/Industrial/Agriculture Wastes

Nearly all 45 Shellfish Management Areas have Wastewater Treatment Plants that discharge directly into shellfish waters; or the plants affect the growing area by discharging into rivers which drain into the growing areas. DMR has placed buffer zones around all of the discharges located in the coastal zone. Many of the treatment plant outfalls have completed hydrographic studies. Outfalls waiting for these studies to be completed have buffer zones based on mathematical calculations using worst case situations and untreated or partially treated sewage.

There are very few industrial discharges along the coast of Maine. Most of them are located in heavily populated areas that have an existing closure due to other influences. Agricultural runoff is not a problem for many growing areas along the coast. The bold rocky coast of Maine is not conducive for large amounts of livestock. There are vast blueberry fields near the coastal waters, however stream sampling has not shown their overland runoff to pose a problem to the surrounding water.

Domestic Waste - Individual Sewage Disposal Systems

As is often the case in this part of Maine that the subsurface soil composition is not always adequate for establishing proper leach fields. Consequently the majority of the recently installed septic systems are designed to have raised bed leach fields. Prior to the

advent of recent sewage disposal technology, the coastal area of Maine relied on a system known as an Overboard Discharge (OBD). The Maine Department of Environmental Protection (DEP) currently licenses, regulates, and inspects these OBDs which are approved sewage treatment systems consisting of a sand filter or mechanical treatment system and a chlorine disinfection unit used to treat discharges of sanitary waste from residential and commercial facilities. The chlorinated waste is discharged through a pipe extending to below the low tide mark. OBDs have been regulated in Maine since the late 1970s when direct discharges of untreated wastes were banned. New OBDs are prohibited by law however, existing systems that remain licensed and inspected may continue to be used until the owner is offered a grant from the Maine Overboard Discharge Program administered by the DEP. The program offers money to replace the OBD with a traditional septic system; or find and/or design an alternative system that can be installed. The Maine Overboard Discharge Program awards grants based upon a priority system. OBDs located in the most productive shellfish habitats are the highest priority for removal.

Existing OBD outfalls do have a prohibited closure zone placed around the end of the pipe. The size of the closure zone is based on calculations generated from the permit information. The water depth (for dilution, including viral), permitted flow rate and the average fecal coliform concentration for a chlorinated system of this type, are all factors used to establish a buffer zone to protect public health.

Drainage Ditches - Stormwater Runoff

Stormwater runoff from drainage ditches, creeks and streams are considered to have the largest impact on water quality in the growing areas of Maine. Stormwater transports pollutants, including fecal coliform bacteria, from many of the indirect pollution sources in the drainage basin, to the growing area. The impact of these outfalls is evaluated by strategically placing sampling stations in these ditches, creeks and streams and also at their confluence with the growing area.

As with many indirect sources of pollution, the overall impact from these specified drainage-ways on the growing area is only known through the review of long-term historical data. Most of the data centers around heavy rainfall events. This is due to the fact that these drainage-ways, which may be dry most of the year, will begin to flow, becoming a conduit for potential pollution to reach the viable shellfish areas. Actual flow rates are now being collected and are being used to generate fecal loading calculations.

Wildlife/Domestic Animals

General descriptions of migratory waterfowl and typical populations of other regional wildlife are included in the shoreline survey reports. Regional wildlife populations are considered significant contributors to the fecal coliform levels in the growing areas during rain events within the local drainage basin. Migratory waterfowl are contributors also; however, the overall impact of wildlife, in general, is ultimately unknown.

Domestic animals within the management areas are typically dogs and cats. Few homes have horses and fewer still have other barnyard type animals as domesticated pets.

Marinas

All marinas within close proximity to open and Approved shellfish harvesting waters were evaluated as the focus of the FY2002 Growing Area Program Evaluation. The evaluation noted that the marina community within Maine will only operate part of the year due to adverse regional weather. The operating procedures the marinas have in place provide an excellent opportunity for the shellfish growing waters to be accessible, at least part of the year, to direct market harvest through the use of conditional management plans.

The closure zones were created by the state using volumetric calculations and re-verified during the evaluation. The basic formulas used were found in FDA guidance issued in June 1989, which describes the proper procedure when establishing a precautionary closure zone around a marina for the purpose of protecting public health. The following formula was used to calculate the size of the recommended closure.

$$\text{Number of Boat Slips} = B$$

$$\text{Number of People on board} = P \text{ (2 people assumed to be on-board)}$$

$$\text{Fecal loading per person per day} = 2 \times 10^9 \text{ FC}$$

The number of boat slips and the assumption of people on-board are used when the actual number of boats with disposal systems (heads) has not been documented.

$$\text{Dilution Volume Required} = \frac{B \times P (2 \times 10^9 \text{ FC})}{\frac{14 \text{ FC}}{100 \text{ mL}} \times \frac{1000 \text{ mL}}{\text{liter}}} = \text{DV (liters)}$$

$$\text{Average Mid-tide Depth in Vicinity of Marina} = \text{AD (meters)} \quad (\text{conversion - 1 meter} = 3.3 \text{ feet})$$

$$\text{Closed Area Required} = \frac{\text{DV (liters)}}{\text{AD (meters)} \times \frac{1000 \text{ liters}}{\text{cubic meter}}} = \text{CAR (m}^2\text{)}$$

$$\text{Radius - Half Circle of Closed Area (straight shoreline)} = \sqrt{2/\pi \text{ (CAR)}} = R \text{ (meters)}$$

Any marina where the half circle radius would not be appropriate, a closure of the calculated surface area (m²) was used.

Radionuclides/Metals

There were no known sources of radionuclides or heavy metals impacting any of the growing areas evaluated. There is some metals data in the central files for those growing areas near industrial or more heavily populated areas. General statements to this effect are made in each of the growing area reports.

Vibrio Species

The State of Maine has not been the original source of shellfish associated with any *Vibrio vulnificus* (V.v.) illness in the past three years. Maine was the possible source of one *Vibrio parahaemolyticus* (V.p.) illness. A thirty year old female consumed soft shell clams as an appetizer, along with a broiled seafood platter as the main course, on July 3, 2002 with an illness onset on July 5, 2002. The suspect clams were harvested from the Sheepscot River in Maine. No other *Vibrio* species illnesses have been documented as a result of individuals consuming shellstock from the waters of Maine. The DMR currently operates under Time-Temperature Matrix Option 3 - Level 2 year round.

Marine Biotoxin Evaluation

The DMR has developed a marine biotoxin contingency plan for all marine and estuarine shellfish growing areas. The blue mussel, *Mytilus edulis*, is used as the indicator species when monitoring for paralytic shellfish poisoning (PSP). PSP levels in mussels usually become toxic one week before soft-shelled clams, *Mya arenaria*. Mussels are sampled weekly from April through October along the entire coast. Additional samples are collected as conditions dictate, whether to further delineate a closure or simply assess an area that has experienced a slight rise in PSP concentrations.

Maine adheres to the PSP international toxic level standard of 80 micrograms per 100 g of edible portion of shellfish. Current state law allows the DMR to immediately close any area that contains toxins or contaminants known to be a public threat. This type of emergency closure effectively revokes all shellfish licenses; it also grants authority to embargo, confiscate and destroy contaminated or potentially contaminated shellfish.

When a closure is deemed necessary, biotoxin monitoring staff members will notify the state's shellfish program director. The director will then contact the marine patrol division offices and alert them to the closure. The marine patrol units will work in concert with the director's office in issuing notices to the general public through newspaper releases, by contacting local government authorities and posting notifications in highly visible public places. The patrol officers will then conduct intense patrols of the affected harvesting areas by water and from land.

The DMR has established policy to assist in the coordination of a contaminated shellfish product recall. DMR requires the certified dealer to contact the receiving state's control authority and provide all pertinent recall and tagging information. The dealer will request the suspect product to be destroyed or returned to the state of origin for further assessment.

The DMR is in close contact with the Canadian shellfish authorities and other state officials along the eastern seaboard. Information regarding increased toxicity in a growing area and changes in phytoplankton populations is shared and analyzed. Collaboration by the DMR and the University of Maine has resulted in the creation of a volunteer-based phytoplankton monitoring program. There are 25 groups state wide who report weekly to the DMR on their findings from plankton tows performed at stations assigned by the DMR.

4. Shoreline Survey

All potential and actual pollution sources have been evaluated by the DMR and documented in the initial Sanitary Survey Reports. Pollution source information is constantly updated throughout the year by both boat and vehicle. The pollution source information gathered throughout the year is then incorporated into the next appropriate report.

The Shellfish Management Areas within Maine are quite large. The water quality staff members have been forced to break up the areas into smaller, more manageable sized areas when conducting any shoreline survey reconnaissance. As a result, it may take several years for the pollution source assessment along the entire growing area shoreline to be completed. It was noted during this evaluation that multiple subsections within one growing area evaluated this year did not have a shoreline survey completed within the past 12 years.

The water quality staff agreed this to be a problem. Once the lacking information was discovered, the staff members scheduled the area for immediate work. Staff members completed the shoreline assessment and were able to leave the affected growing waters in the Open Status.

The shoreline survey database is set up to be very comprehensive. The eastern-half of the state routinely updates the shoreline database from their field data sheets. It was noted that only a portion of the western-half of the state's shoreline survey information has been entered into the computer. Currently hardcopies of their shoreline data must be reviewed to determine if correlations exist between water quality and identified pollution source locations.

D. State Program Deficiencies

The following program wide deficiencies were noted during the FY2003 Growing Area Evaluation:

1. During the review of the Sanitary Surveys it was noted that a standard statement was found in the meteorological characteristic's section which addressed winds. The statement implied that [after a data review] there was no indication that winds had direct adverse affect on the growing area. Further review of the field data sheets and the field data sheet database revealed that any potential influence of wind on the growing area was not being documented or even considered. As part of the requirements specified in Chapter IV@.01.A(1)(c) the affects of wind on the growing area should be documented and evaluated as part of the written Sanitary Survey report.
2. During the review of the Sanitary Surveys it was noted that data analysis and interpretations required under Chapter IV@.01.A(1)(d) are either lacking substance or are missing from the reports. Each hydrodynamic and meteorological factor that could have adverse affects on the growing area should be analyzed and discussions relating to that analysis should be added to the survey report. These discussions would include, but are not limited to, water quality changes, reasons for any change and a trend analysis on the individual factors. The trend analysis should also describe how the factors relate to, or may affect, each other and if combined, how the factors create an adverse situation and to what extent.
3. During the review of the Sanitary Surveys it was noted that the Sanitary Survey conclusions necessary to illustrate the proper growing area classification, as required in Chapter IV@.01.A(1)(e) are very brief and nondescript. This section should routinely include recommendations for further work, any changes in monitoring strategy, the addition/ deletion of water quality stations (along with rationale) and a detailed description of the new growing area classification.
4. During the review of the Sanitary Surveys it was noted that the computer generated maps used to provide a visual description of the shellfish management areas do not depict an upland boundary. A distinct boundary through the upland topography would allow for a more clear determination to where pollution may be impacting shellfish waters; and for adjoining growing areas, which water body may be affected by the particular pollution source. [Chapter IV@.01.D(2)(a)]
5. During a review of the Shoreline Survey Database it was noted that the pollution sources were not identified as being either direct or indirect. Chapter IV@.01.D(2)(d)(ii) requires the Authority to determine at a minimum if the pollution source has a direct or indirect impact on shellfish waters.

E. Recommendations

FDA recommends that the DMR obtain Global Positioning System (GPS) coordinates for all fixed points referenced on all computer generated (ArcView™) maps. Actual coordinates generated in the field are more defensible in court and maintain the quality of information within the mapping database. Items to GPS would include but are not limited to: Sample stations, point source outfalls and closure line endpoints or changes in closure line direction.

FDA recommends that the DMR expand the discussion on the four standard Hydrographic and Meteorological Characteristics by including more detail as to how each may affect the particular growing area. The Summary discussion section should include an assessment as to how the four different characteristics relate to each other and if adverse conditions are created when two or more characteristics happen simultaneously.

FDA recommends that the DMR create a procedure for documenting the creation, deletion or modification of water quality sample stations. Items to document would include but are not limited to: Station type, designation (number), Lat/Long (coordinates), description (location), justification for action taken and approval. Such documentation would be reviewed with the growing areas Sanitary Survey.

FDA recommends that the DMR establish a procedure for reports to be subjected to an internal Peer Review process. It is important that the report writers not become complacent with their work. A peer review process will allow an independent third party to review the written work before it becomes final and offer suggestions for improvement.

FDA recommends that the DMR include a title page with all Sanitary Surveys. The title page would include the name of the author(s), the name of the person conducting the peer review, and the signature of the most responsible program official signifying that the report is now final and in effect.

FDA recommends that the DMR create a template for Sanitary Surveys. The template would encourage program wide consistency between growing area staff. This approach will also streamline some language which will remain constant from one report to the next. It will also ensure that all required sections of the Sanitary Survey are included and thoroughly discussed.

FDA recommends that the DMR utilize a Bibliography Page as part of the Sanitary Surveys. The bibliography page should identify the source of all factual statements. The page should also be used to identify any organizations, state agencies or non-profit groups who generate and/or provide essential information that is incorporated into the overall assessment of the shellfish management areas.

FDA recommends that the DMR create a SOP for conducting shoreline surveys and for managing the information. The SOP should require a detailed schedule outlining upcoming completion dates to ensure that growing areas are not closed unnecessarily due to incomplete shoreline assessments. Upon completion of the shoreline survey, a summation should be

completed which documents relevant findings, courses of action, referrals to other state agencies for remediation [Chapter IV@.01.A(4)] and any other comments describing conditions that directly affect growing area classification.

FDA recommends that the DMR obtain measurements used as part of the assessment process in the most precise manner possible. Stream flow volume (cfs), station location (GPS), and distance (point A to point B) should have actual values whenever practical and estimations should be used only when absolutely necessary. [Chapter IV@.01.D.(1)(b)]

FDA recommends that the DMR establish a problem-solving chain of command. This chain of command structure along with regularly scheduled staff meetings will provide staff members with an opportunity to discuss pressing issues of the day, comment on schedules and prioritize deadlines. The outward sharing of information will assist with creating a consistent atmosphere for industry members and external customers who wish to be treated similarly throughout the state.

FDA recommends that the DMR create a SOP for stream sampling (pollution source sampling). The SOP should define Actual versus Potential pollution sources; and define Direct versus Indirect pollution sources. The SOP should outline a sampling protocol which describes minimum requirements (i.e. 2 dry weather and 2 wet weather samples to be collected to assess potential impact on the shellfish growing area).

FDA recommends that the DMR create a template for Conditional Area Management Plans. A basic outline format with standard language for each of the management plans used in Maine should be available to staff members to ensure consistency. The four plans include: Rainfall, Wastewater Treatment Plant, Marina and Seasonal. The template should detail how the plans are implemented, how shellfish areas are opened and closed, and who is responsible at each step in the process to encourage accountability.

F. Corrective Actions taken by the State

The DMR immediately reassessed the shoreline around the growing waters where the information was outdated. Other deficiencies found during this evaluation will be addressed in an action plan.

G. Action Plans Requested

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to assess any impact from wind. As part of the requirements specified in Chapter IV@.01.A(1)(c) the affects of wind on the growing area should be documented and evaluated as part of the written Sanitary Survey report.

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to

provide detailed data analysis and data interpretations. Data analysis and interpretations required under Chapter IV@.01.A(1)(d) are either lacking substance or are missing from the reports.

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to provide detailed conclusions necessary to justify the proposed growing area classifications [Chapter IV@.01.A(1)(e)]. This section should routinely include recommendations for further work, any changes in monitoring strategy, the addition/deletion of water quality stations (along with rationale) and a detailed description of the new growing area classification.

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to determine the boundary of the Shellfish Management Area based on area topography as per Chapter IV@.01.D(2)(a). A distinct boundary through the upland topography would allow for a more clear determination to where pollution may be impacting shellfish waters; and for adjoining growing areas, which water body may be affected by the particular pollution source.

A corrective action plan, along with a proposed completion date for correction, is requested within thirty (30) days to demonstrate how the Department will comply with the requirement to signify whether a pollution source has either a direct or indirect impact on shellfish waters [Chapter IV@.01.D(2)(d)(ii)].

H. Accomplishments

[The DMR staff members compiled detailed notes during the PEER this year. During the Close-out meeting, Director Fitzpatrick and I discussed each of the deficiencies and recommendations. The water quality personnel take great pride in their program and took the initiative to implement portions of the PEER before it became final. Some of their efforts are illustrated below.]

Before the PEER review, staff meetings were held sporadically. Since the review, the DMR have instituted regularly scheduled monthly staff meetings complete with minutes and sub-committee assignments and deliverables. The DMR management has also developed a draft SOP for document PEER reviews. The SOP describes the procedure for developing, formatting, approving and distributing documents within the Public Health Division. This will promote consistency and improve the quality of reports division wide (not just shellfish related documents.) The SOP includes templates for each type of report; i.e. Sanitary Survey, Triennial review, Annual update, etc.

A dispersion and dye study was completed for the Freeport Sewage Treatment Plant on the Harraseeket River in May 2003 and the Wiscasset Sewage Treatment Plant on the Sheepscot River in October 2003. There are no completed reports to date. These studies were done in collaboration with USEPA and the Maine Department of Environmental Protection. The Wiscasset study was the fourth study to be completed in two years.

The DMR are one year into conditional area verification studies to correlate water quality results with reduction of bacterial levels in shellfish due to rainfall in the Medomak River watershed in

Waldoboro and in the St. George River watershed in Thomaston. These studies began because of increasing pressure from harvesters who feel that Conditional areas are closed for an excessive amount of time.

Handheld GPS units were purchased for each office. Training was held on the handheld units in September 2003, which included how to take and store waypoints. The second stage of training, how to download the waypoints to the computer has not been completed to date. One person has been signed off on this portion of the training.

The DMR have developed a procedure and a form for documenting the creation, deletion or modification of water quality sample stations. Items included on the document: Station type, designation (number), Lat/Long (coordinates), description (location), justification for action taken and approval. Prior to this form, no formal documentation was maintained which resulted in valuable historical information to be lost.

An intensive follow-up review of the tide stage sampling data was completed in the summer of 2003. Problem areas were identified and are currently being addressed through an updated sampling SOP, including:

1. Document in the database (on a scale of 1-5) the lowest tidal stage each station can be collected.
2. Verify the tide stage reference assigned to each station by the computer is accurate based on the time of sampling and the NOAA Tide Charts.
3. Targeting efforts to sample each station (at least 50% of the samples FY'04) on lowest tide stage possible (L, LE, LF).
4. Mercuria Cumbo is currently working to develop a statistical analysis to determine what effect tide stage has on water quality. Mercuria will develop a training course for the growing area staff so that each staff member will be able to use this procedure to perform detailed data analysis and compare many different variables including tidal stage, rainfall and wind.

The Public Health Division is migrating toward a new online closure editor system. This system will make all maps and closure notices (bacterial and PSP) available to the general public through the internet.

The first edition of color maps have been provided to the Marine Patrol Officers in Division I. A standard for all maps statewide, to be in color and of a higher detail and quality, continues to be pursued.

The Public Health Division has held eight informational meetings educating shellfish harvesters about a new rule which will affect them directly; Chapter 9 - Harvester: Shellstock Harvesting, Handling and Sanitation. Four additional educational meetings will be held in November and December 2003 with the anticipated date of public hearings to be in February 2004 and final rule promulgation in April 2004.

I. New or Emerging Problems

There were no new or emerging trends identified as a result of this evaluation.

J. Technical Assistance and/or Training Requested by the State

The DMR would like to request that a Part II growing area course be developed to supplement the Sanitary Control of Shellfish Growing Area course. This should include more advanced data analysis and interpretation, hydrographic evaluations, the impacts of metals, organics, pesticides, and conditional area/marina/seasonal conditional areas.

The DMR would like to request that a Northeast growing area regional peer group be established similar to the Northeast State Standardization Officers (NESSO) and Northeast Laboratory Evaluation Officers and Managers (NELEOM) groups. This would create a forum for regional discussion of issues pertaining specifically to the NE; i.e. OBD closures, management of conditional areas, etc.

K. Conclusions

The DMR Growing Area Classification Program does not meet all of the requirements of the NSSP Model Ordinance. Over the past year, the water quality staff have worked diligently to improve the state's approach to shellfish growing water classification. Due to budgetary constraints the staff members have had to become creative and even innovative in their attempts to comply with the NSSP requirements and their own state regulations. Even though there is much room for improvement, the evaluation revealed that the staff members are heading in the right direction and it is only a matter of time before their program will rival any other.

L. Summary of the State's response to FDA evaluation

We appreciate the time and effort that was spent by Specialist Koufopoulos in Maine and with staff to get a thorough and complete review of the Growing Area Classification Program. He took the time to clearly explain his expectations and program requirements to staff members and the Division Director.

We concur with all of the findings in this report and appreciate Specialist Koufopoulos' constructive and diplomatic tone in presenting his recommendations and our program wide deficiencies. We work best with concrete issues to address and will work diligently to bring the program into compliance.

The Maine Shellfish Program is developing a Quality Assurance Plan. We began addressing the deficiencies and recommendations given by Specialist Koufopoulos after the verbal close out meeting with the Division Director. We look forward to working with him as we continue to address these issues.